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Glaxo, Boehringer to Let Africa Make More Generics for AIDS

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LONDON -- Two big pharmaceutical companies, under legal pressure from AIDS activists, agreed to allow more generic versions of their patented AIDS medicines to be made in South Africa and other sub-Saharan countries, a move that could lower the cost of the medicines there.

As part of an out-of-court settlement yesterday with South Africa's Treatment Action Campaign, Britain's GlaxoSmithKline PLC and Germany's Boehringer Ingelheim GmbH agreed to expand the licensing of their patented AIDS drugs to three generic manufacturers in South Africa and other African countries. In return, the South African Competition Commission, a government body that monitors free-market practices, agreed to drop a yearlong probe into whether the companies had overcharged for their AIDS drugs. Glaxo and Boehringer Ingelheim already have existing agreements with a fourth generic manufacturer, South Africa's Aspen Pharmacare.

Separately, the biggest head-to-head comparison of AIDS medications to date found that a three-drug cocktail used by many HIV-infected people proved clearly superior to other combinations at treating new patients. The combination works better and longer, is easier to take and suppresses the virus more quickly, the international study found, offering powerful confirmation of what many AIDS specialists had already believed.

Among the study's other findings: Four drugs are not necessarily better than three.

The study involved patients at 58 hospitals and clinics in the U.S. and 23 in Italy. Researchers led by doctors at Harvard and Stanford universities tested several three- and four-drug combinations of six HIV medicines. They found the best combination for people getting their first HIV medication was efavirenz, lamivudine and zidovudine, better known as AZT. The second two drugs are taken in a combination pill under the brand name Combivir, sold by GlaxoSmithKline. Bristol-Myers Squibb Co., which has its research headquarters in Princeton, N.J., sells efavirenz under the Sustiva brand.

Under the settlement pact in South Africa, Glaxo also agreed to cap royalty fees at no more than 5% of net sales and to extend the generic licenses to the private and public sectors. It said it would allow the generic licensees to export AIDS drugs manufactured in South Africa to 47 sub-Saharan African countries. The Competition Commission said it had not asked for a fine or administrative penalty against Glaxo, which is the world's largest maker of AIDS medicines.

By introducing more competition from generic drug makers into Africa's AIDS drug market, the settlement is likely to lower the cost of these drugs sharply and broaden access to these medicines for Africans infected by HIV.

The move follows the South African government's landmark decision last month to provide AIDS drugs to all its citizens who need and want them. The country has more HIV-positive people -- an estimated 5.3 million, according to the latest government estimate, out of a population of about 45 million -- than any other nation. Until now, only a tiny fraction of South African AIDS patients received anti-HIV medication, largely because the drugs were too costly.

The new licensing agreements could make it easier for the South African government to take advantage of a deal struck by former President Clinton's foundation with Aspen Pharmacare and four Indian generic-drug makers. That deal slashed the price of generic AIDS medicine for several African and Caribbean nations. For

example, the price of one commonly used three-drug regimen dropped to 38 cents per day per patient from an already cut-rate generics price of 55 cents.

But South Africa has strict patent laws, which many legal experts said limited its choice of suppliers. Yesterday's announcement is likely to expand greatly the number of legal suppliers that can compete for the government's tender.

A Glaxo spokesman said the company was pleased to have settled the case. A Boehringer Ingelheim representative wasn't available for comment.

Yesterday's settlement follows an Oct. 16 ruling by the South African Competition Commission that Glaxo and Boehringer Ingelheim had abused their dominant positions in the market for AIDS drugs by overcharging customers. The commission also found that the companies had refused to license their patents to generic manufacturers for a reasonable royalty. Glaxo and Boehringer Ingelheim denied the charges.

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